Evaluation of safety and efficacy of first-line antiretroviral single tablet regimens (STR) in the correctional setting: Is one tablet once daily the best option?

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BACKGROUND

- Many inmates are initiated on antiretroviral therapy (ART) for Human Immunodeficiency Virus (HIV) and are successful in achieving virologic suppression and immunologic improvement.
- Initiation of ART in HIV positive inmates has shown that up to 59% achieve a viral load (VL) < 400 copies/mL.[1]
- In the Connecticut Department of Corrections, a significantly higher proportion of patients achieved VL < 400 copies/mL at release (70%) compared to during time of incarceration (29.8%, p < 0.001).[2]
- HIV patients in the Illinois Department of Corrections (IDOC) had a significantly higher proportion of patients achieve VL < 48 copies/mL when managed by HIV subspecialists (91.1%) compared to general practitioners (59.3%; p < 0.001).[3]
- Antiretroviral therapy is individualized to each patient's needs, co-morbidities, and interacting medications.[4]
- Decreased pill burden is associated with increased adherence, but it is unknown if a single tablet regimen (STR) achieves higher rates of virologic suppression in those incarcerated.[4,5]
- Atazanavir-containing regimens have been reported to be as efficacious as efavirenz-containing and elvitegravir-containing STR in achieving viral suppression and safety.[6,7]
- Single tablet regimens are still associated with side effects and some have higher costs compared to other first-line regimens.

NEED FOR STUDY

- Efficacy of different STR and multiple tablet regimens (MTR) have been compared but it is unknown if this has any effect on sustained virologic suppression.
- Attempt to show that regardless of single or multiple tablet regimens, efficacy, safety, and adherence can be achieved for STR or MTR in the incarcerated population.

PRIMARY OBJECTIVE

- Determine if a STR is associated with similar virologic suppression compared to first-line MTR in an incarcerated population managed by an HIV telemedicine service.

RESEARCH DESIGN AND METHODS

Single-center, non-randomized, comparative design:
- Retrospective cohort
- Evaluated in HIV telemedicine clinic from 7/11/10 – 7/1/13
- IRB Approval: July 16, 2013

Inclusion Criteria:
- HIV-positive
- At least 18 years of age
- Incarcerated in IDOC
- Taking one of the regimens listed in the regimens evaluated table
- Have a medical record at University of Illinois Hospital and Health Sciences System

Exclusion Criteria:
- Received an HIV regimen not listed in the regimens evaluated table

Data Collection
- Viral load (VL), CD4, CD4% (every 24 weeks)
- Adherence (patient reported, refill history)
- Patient/laboratory reported side effects
- ART resistance

OUTCOMES

Primary Outcome: Non-inferiority of MTR compared to STR in patients with sustained virologic suppression (Viral load < 48 copies/mL).

Secondary Outcomes: Assess laboratory/patient reported adverse reactions (ADRs), patient reported adherence and refill history, and ART change due to development of resistance or intolerable adverse reactions.

REGIMENS EVALUATED

STR	Efavirenz/emtricitabine/tenofovir (EFV/FTC/TDF, Atripla®)
	Rilpivirine/emtricitabine/tenofovir (RPV/FTC/TDF, Complera®)
	Elvitegravir/cobicistat/emtricitabine/tenofovir (EVG/COBI/FTC/TDF, Stribild®)
MTR	Emtricitabine/tenofovir + darunavir/ritonavir (FTC/TDF + DRV/r, once daily)
	Emtricitabine/tenofovir + atazanavir/ritonavir (FTC/TDF + ATV/r)
	Emtricitabine/tenofovir + raltegravir (FTC/TDF + RAL)

STATISTICAL ANALYSIS

- Baseline characteristics and collected data were compared using a chi-squared test (for categorical variables) or ANOVA and Spearman Rank Correlation (for continuous variables).
- All statistical analyses assumed a significance level of 0.05.

RESULTS

- N = 553; average age 41.2 years; 88% male; 80% African American

	STR	MTR	P value
Patients (n)	381	172	-
Average follow up (weeks)	37.5	43.2	-
% VL < 48 copies/mL			
Baseline	77	82	0.1471
Week 96	99	99	0.5628
Last study visit	90	91	0.5930
% CD4 < 200 cells/mm^3			
Baseline	7	20	< 0.0001
Week 72	0	2.4	< 0.0001
Patient reported adherence (%)	99	99	-
Reported ADRs (%)	16	54*	< 0.0001
Overall Discontinuation Rate (%)	8	14%	-

*61/95 related to elevated total billirubin without scleral icterus due to ATV, a common and benign lab reporting

PATIENTS WITH ART CHANGE

Regimen	n	ART Change (%)		
		ADR	Resistance	Other
Single Tablet Regimens				
EFV/FTC/TDF	367	19 (5.2)	10 (2.7)	2 (0.5)
RPV/FTC/TDF	11	0	0	0
EVG/COBI/FTC/TDF	3	0	0	0
Multiple Tablet Regimens				
ATV/r + FTC/TDF	125	12 (12.9)	4 (3.2)	4 (3.2)
DRV/r + FTC/TDF	31	4 (12.9)	0	1 (3.2)
RAL + FTC/TDF	16	0	0	0

CONCLUSIONS

- Incarcerated patients followed in an HIV telemedicine clinic in IDOC had similar rates of virologic suppression regardless of STR or MTR.
- As similar rates of viral suppression, adherence, medication resistance, and discontinuation were found, using first-line MTR in the correctional setting is a viable alternative to STR.
- These findings could be applied to other controlled settings and may provide cost-savings as more generic antiretrovirals become available.

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DISCLOSURES

Authors of this presentation have nothing to disclose concerning possible financial or personal relationships with commercial entities that may have a direct or indirect interest in the subject matter of this presentation.